#### Breath Alcohol Procedure Manual

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#### **SECTION 1**

#### **INTRODUCTION**

#### 1.1 OVERVIEW OF THE ALASKA BREATH ALCOHOL PROGRAM

The Scientific Crime Detection Laboratory (crime lab) is part of the Department of Public Safety and per 13 AAC 63.010 the commissioner will designate an employee of the crime lab as the scientific director of the blood and breath alcohol testing program. The scientific director is responsible for all aspects of the breath alcohol program including calibration and certification of breath test instruments; training and certification of breath test operators and breath test supervisors; and maintaining the scientific integrity of the breath test program.

The breath alcohol section staff falls under the supervision of the scientific director and as his/her designee(s) carry out the tasks associated with running the statewide breath testing program.

### 1.2 EVIDENTIAL BREATH TEST INSTRUMENT

Per 13 AAC 63.020 and 13 AAC 63.030 the scientific director must approve a type of breath test instrument for use in the state of Alaska as well as maintain a list of all approved breath test instruments and associated equipment. The current breath test instruments approved for use in the state of Alaska are the DataMaster cdm and the DataMaster DMT both manufactured by National Patent Analytical Systems, Inc. The contents of this manual are specific to the DataMaster DMT. The approved associated equipment list is maintained in Appendix I of this manual.



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#### **SECTION 2**

#### **ADMINISTRATIVE PROCEDURES**

#### 2.1 VERIFICATION OF CALIBRATION REPORTS

Per 13 AAC 63.100 the accuracy of the calibration of the breath test instruments must be verified at least every 60 days. The documentation of this accuracy check is the verification of calibration report. The accuracy check performed for the verification of calibration report consists of a diagnostic check and five tests of the external dry gas ethanol standard. The verification of calibration procedure is incorporated into the instrument software under the direction of the scientific director. A verification of calibration is initiated by the instrument software in intervals of less than 60 days and whenever the external dry gas ethanol standard is changed. Breath test operators and breath test supervisors can also initiate a verification of calibration.

The instrument software is scheduled to initiate a verification of calibration on the following dates at 12:00 pm:

January 3<sup>rd</sup>
February 21<sup>st</sup>
April 11<sup>th</sup>
May 30<sup>th</sup>
July 18<sup>th</sup>
September 5<sup>th</sup>
October 24<sup>th</sup>
December 12<sup>th</sup>

At the completion of a successful verification of calibration the instrument stores a copy of the written report to memory. If a verification of calibration does not complete successfully then the instrument will not allow a subject test to be initiated until a valid verification of calibration has been completed.

The instrument memory is periodically uploaded to a crime lab computer via a modem line to the DM Host software. The completed verification of calibration report is printed from the uploaded file and technically reviewed by the members of the breath test section prior to being signed and notarized by the scientific director. The signed copies are scanned and a copy is placed on the crime lab website and in the Laboratory Information Management System (LIMS). The original signed copy is retained in a file at the crime lab by the scientific director.

The dates listed above are not the only acceptable dates for verification of calibrations. The only requirement is that a verification of calibration be performed every 60 days when an instrument is in service.

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### <u>Technical Review of Verification of Calibration Reports</u>

A technical review of each verification of calibration report is performed by a qualified member of the breath alcohol section prior to the report being reviewed and signed by the scientific director. The technical review includes the following components:

- Verification that the external dry gas ethanol standard cylinder lot number and expiration date is included in the list of approved cylinders kept at the crime lab.
- Verification that the five external standard results fall within +/- 0.005 of the target value adjusted for barometric pressure.
- Verification that the standard deviation of the five external standard results is equal to or less than 0.0030.
- Ensure that each component of the diagnostic check read "passed".
- Ensure no status messages are present.

The technical reviewer's initials and the date the review was performed are placed in the lower right-hand corner of the verification of calibration report indicating that the technical review was performed.

The scientific director completes a review that includes all components of a technical review and then signs the approved report in front of a notary. A verification of calibration is not a completed approved report until signed by the scientific director and notarized. The completed verification of calibration report certifies the instrument for continued evidentiary use in the State of Alaska.

#### 2.2 DM HOST

The DM Host software is provided by National Patent Analytical Systems, Inc. The DM Host software communicates, through modem lines, with the breath test instruments to upload the data written to memory. The DM Host software also enables the breath analysts to remotely access the instruments in the field for troubleshooting purposes. Breath analysts can view the technician screen remotely for troubleshooting purposes; however, the voltages and settings can only be adjusted when an instrument is at the crime lab.

#### Uploading Data From Breath Test Instruments

The DataMaster DMT writes subject tests, diagnostic tests, verifications of calibration, supervisor tests, linearity tests, status messages, calibration records, tank change records and software update records to the instrument memory. The DM Host software enables the breath test section to manually upload the data collected by the breath test instruments in the field. The data is then stored in the DM Host database which is housed on a

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secure server at the crime lab. Once the data is uploaded to the crime lab it is no longer available in the DataMaster DMT memory.

All data retrieved by DM Host from the breath test instruments is considered an official record and that data is not altered by the breath alcohol section staff. The data collected can be searched, reports generated and printed. Breath test instruments in the field will be uploaded periodically.

#### 2.3 LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS)

The LIMS currently in use at the laboratory is JusticeTrax. The JusticeTrax system is used by the breath alcohol program to electronically file the paperwork associated with running the breath test program.

The JusticeTrax program is used to track breath test operators and breath test supervisors along with their training records. The program also tracks the status and location of each instrument along with any paperwork associated with that instrument.

The working instructions for the operation of JusticeTrax are maintained in the Discipline as a separate controlled document.

#### 2.4 LEGAL

One of the duties of the breath alcohol program is to work with the legal community to provide testimony and information about the breath alcohol program, the evidentiary breath testing instrument and alcohol impairment.

#### Discovery

Discovery requests are bandled by the scientific director or his/her designee. The breath alcohol program follows the laboratory discovery policy. For more information on the laboratory discovery policy refer to the Laboratory Policy Number 10: Disclosure of Examination Results.

#### **Testimony**

The breath alcohol analysts provide testimony on the breath alcohol program, the widentiary breath testing instrument and alcohol impairment. This testimony is provided in state, municipal and federal courts upon request and approval by the section supervisor.

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#### **Opinions Issued**

On occasion the breath alcohol program is asked to provide written opinions on various aspects of breath alcohol or impairment related topics. These opinions are generated as memos either from the breath alcohol section as a whole or from the individual breath alcohol analyst depending on the specific topics covered. Opinions are not issued as reports and therefore they are not technically reviewed. Opinion memos are scanned into the LIMS after completion.

#### Department of Motor Vehicles

The Department of Motor Vehicles (DMV) holds administrative proceedings regarding impaired driving cases and can request information regarding these cases. Requests from the DMV are handled following the laboratory discovery policy. Occasionally, expert testimony is provided for these hearings upon request and approval by the section supervisor.



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#### **SECTION 3**

#### **TECHNICAL PROCEDURES**

#### 3.1 INSTRUMENT CHECK-IN

When an instrument is initially received by the laboratory from the manufacturer a DataMaster Acceptance form is filled out by the receiving analyst. This information is then stored in the LIMS.

When instruments arrive at the laboratory from the field or are returned to the laboratory from a factory repair, the breath test instrument will follow a check-in procedure. The check-in procedure includes updating the instrument's status in the LIMS, running a diagnostic and 5 tests of an 0.080 external standard, printing the calibration factors and uploading the instrument to retrieve all information stored in memory (if coming from the field). The check-in paperwork should be documented on the DataMaster Check-In Form which is scanned into the LIMS. This documentation is then technically and administratively reviewed by a qualified analyst.

A qualified breath analyst will then perform a visual inspection and evaluate the instrument for repair. If a repair is required and can be performed at the laboratory, the analyst will complete the repair process. If the repair requires factory assistance, the instrument will be sent to National Patent Analytical Systems, Inc. for repair. Any repairs performed in-house should be documented on the DataMaster Repair Form which is then scanned into the LIMS. This documentation is then technically and administrativly reviewed by a qualified analyst.

The breath test supervisors communicate with the breath alcohol section about the status of their agency's instrument utilizing a change in instrument status form. This form includes information on when an instrument was placed in service, taken out of service and what problems, if any, reported with the instrument.

All correspondence from breath test supervisors recorded on the change in instrument status forms will be documented in the LIMS by the breath alcohol section.

### 3.2 INSTRUMENT CALIBRATION

Per 13 AAC 63.100 the scientific director has designated the DataMaster DMT can be calibrated by either National Patent Analytical Systems, Inc. or a qualified breath analyst at the crime laboratory. The DataMaster DMT calibration is a single point calibration. Once instruments are calibrated they are not recalibrated unless previously stored calibration factors are no longer accessible by the DataMaster DMT rendering the

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instrument inoperable or a breath analyst determines the instrument is not functioning properly.

#### Calibration Procedure

The crime lab performs calibration of the DataMaster DMT using a wet bath ethanol simulator solution and a blank simulator solution. The blank simulator solution is 500 mL of deionized water.

Wet bath ethanol simulator solutions used by the crime lab are commercially prepared, traceable to National Institutes of Standards and Technologies (NIST), and come accompanied by a certificate of analysis. These solutions have a concentration that yields an ethanol vapor concentration at 34°C of 0.10 g/210L on a breath test instrument. The certificates of analysis for simulator solutions are scanned into the LIMS.

The crime lab uses simulators manufactured by Guth Laboratories that are NIST traceable. They are returned to Guth Laboratories annually for calibration and maintenance. Certificates of calibration for the simulators are scanned into the LIMS.

The DataMaster DMT software allows the breath analyst to select the number of replicate samples of the simulator that the instrument requires for calibration. This option is found under the DMT Icon Setup menu for calibration. This should be set to run three replicates for both the blank and  $0.10~\rm g/210L$  simulator solutions.

When a qualified breath analyst determines that an instrument requires recalibration the analyst should create a calibration request in the LIMS and assign the request. A new bottle of simulator solution should be poured into a simulator and the date that the bottle was opened indicated on the label of the simulator. A new bottle of simulator solution should be used each day that instruments are calibrated. The analyst should ensure the instrument and simulators have been turned on and warmed up prior to performing calibration. The lot number and expiration date of the simulator solution and serial number and calibration date of the simulator used is documented on the Calibration Form which is scanned into the LIMS.

The DataMaster DMT instrument software prompts the breath analyst to attach both the blank and 0.10 g/210L ethanol simulator solutions to the breath instrument's calibration port at the appropriate times during the calibration sequence. The breath analyst should follow the instrument prompts. When the calibration process has been completed the breath analyst should print a copy of the calibration factors from the new calibration. The calibration factors should be scanned into the laboratory calibration request in the LIMS. Each laboratory calibration process is technically reviewed by another qualified analyst. When the technical review has been completed a certificate of calibration will be generated.

When calibration is performed by the manufacturer it is returned to the laboratory with a certificate of calibration. This certificate should be scanned into the LIMS under a

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factory calibration request. Every time the instrument is calibrated (whether by the factory or crime lab) the instrument must have the calibration verified with a certification procedure.

#### 3.3 INSTRUMENT CERTIFICATION

As per 13 AAC 63.100 every breath test instrument must have the calibration verified prior to being certified for use. This must be performed by the scientific director or a qualified person designated by the scientific director. Instrument certification is the process that the breath alcohol section uses to verify that the individual breath instrument's calibration has been verified. The scientific director has designated that instrument certifications can be performed by qualified breath analysts from the crime lab.

An instrument is required to have a certification process performed after the instrument is received from the manufacturer, after a repair that has an effect on the analytical components of the instrument, and as part of preventative maintence. Certification is not necessary after software updates unless the update has an effect on the analytical components of the instrument.

The DataMaster DMT certification process includes voltage checks, linearity testing, functional tests, minimum volume determination and a non-drinking subject test.

#### Voltage Checks

The DataMaster DMT has digital potentiometers that can be viewed and adjusted by the breath analysts in the technician screen located under the DMT Icon. During certification the technician screen is checked by the analyst to ensure the voltages displayed are within normal operating tolerences published by the instrument manufacturer. The technician screen is also the location of the barometer setting, the radio frequency detection sensitivity and the breath / air volume and flow rate readout.

The barometer reading of the breath test instrument should be checked with the NIST traceable barometer located at the crime lab and the setting should be adjusted if the instrument barometer differs by more than +/- 0.10 inches of mercury. The barometer used by the crime lab for this comparison must be purchased from an ISO 17025 certified supplier, be NIST traceable and come accompanied with a certificate of calibration. The barometer should be sent out for recalibration or replaced when the manufacturer calibration expires. The certificates of calibration for the barometer will be scanned into the LIMS.

The radio frequency sensitivity is adjusted from the technician screen. Prior to adjusting the sensitivity the analyst should ensure that all radios are turned off in the vicinity of the instrument. The initial adjustment should be performed by hitting the set button. This

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will trigger a series of beeps as the instrument sets a default baseline level from which it measures radio frequency.

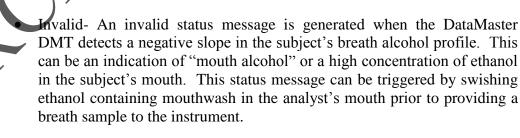
The volume adjustment ensures that the DataMaster DMT is appropriatly reading breath volume. The breath analyst should use a graduated syringe to provide a 1.5 L breath sample to the DataMaster DMT while in the technician screen. The breath analyst should ensure that the volume reading in the technician screen reads within +/- or the volume reading should be adjusted using the set screw inside the instrument.

#### **Linearity Testing**

The linearity test checks the DataMaster DMT's ability to accurately read ethanol at a range of levels. This is accomplished by using the linearity test function. A linearity test should be conducted using external dry gas ethanol standards (as measured at standard presssure) at the following levels: 52 ppm, 103.5 ppm, 208 ppm, 260.5 ppm, 521 ppm and 781 ppm. These levels are the equivalent of 0.020, 0.040, 0.080, 0.100, 0.200, and 0.300 g/210L respectivly as measured by a breath test instrument. Each external dry gas ethanol standard is analyzed five times. The allowable range for the external dry gas ethanol standard is +/- 0.005 or 3%, whichever is greater, of the target value adjusted for barometric pressure. The standard deviation of the five values must not be greater than 0.0030. The linearity test in the DataMaster also gives an R-squared value and the requirement for this is at least 0.9990.

#### **Functional Tests**

The DataMaster DMT generates status messages to inform the operator when certain situations occur. As part of the certification process some of these status messages are triggered to ensure the instrument is functioning properly. It is not possible to trigger every status message the DataMaster DMT can generate because some status messages require there to be a functional problem with the instrument. The following is a list of the status messages that are triggered during the certification process and their purpose.



• Incomplete- An incomplete status message is generated when the subject fails to provide a breath sample that meets the minimum requirements of the instrument within the two minutes alotted. To trigger this status message the instrument should be set up for a subject test and less than a minimum sample provided.

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Interference Detected- An interference detected status message is generated when the DataMaster detects the presence of a substance other than ethanol in the sample provided. Two of the more common interfering substances that could be found in a subject breath sample are acetone and To generate this status message an ethanol wet bath simulator solution containing 200 uL of acetone should be provided to the instrument through the breath hose. This is then repeated using an ethanol wet bath simulator solution with 200 uL of isopropanol. The solutions used for interference testing are made at the crime lab using a commercially prepared wet bath ethanol simulator solutions and adding 200 uL of either acetone or isopropanol. The lot number ethanol level and expiration date of the simulator solution and the serial number and calibration date of the simulator used should be documented in the certification paperwork. The wet bath ethanol simulator solutions used for interference detected testing should be replaced three months after preparation.

• Radio Frequency Interference Detected- A radio frequency interference detected status message is generated when the DataMaster DMT detects the presence of radio frequency in the vicinity of the instrument. This status message is generated by setting up a subject test sequence and keying a radio in the room with the DataMaster. The instrument should generate an RFI status message when a radio is keyed in the room with the DataMaster DMT.

#### Minimum Volume Determination

Volume thecks ensure that the instrument is requiring the appropriate minimum breath volume. The DataMaster DMT is set to accept breath samples at a minimum volume of approximately 1.5 L.

Volume checks are performed using a graduated syringe. The breath analyst should provide samples in increments of 0.1 L through the breath hose to determine the minimum volume that the instrument being certified will accept. The requirement for an instrument to be placed in service is that the minimum volume be greater than or equal to 1.3 L and less than or equal to 1.7 L.

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#### **Non-Drinking Subject Test**

The final step in an instrument certification process is a non-drinking subject test. The breath analyst should ensure a 208 ppm ethanol (0.080 g/210L) external dry gas ethanol standard cylinder is in place or follow the tank change procedure. The analyst should then initiate a subject test using default software options. The subject test printout should be attached to the certification paperwork and the verification of calibration should be technically reviewed and signed by the scientific director. The verification of calibration report is not part of the certification paperwork.

If an instrument fails any portion of the certification process the instrument should be evaluated for repair or recalibration by the breath analyst. Any repair or recalibration should be documented on the appropriate forms and scanned into the LIMS. The instrument must complete a certification prior to being placed in service in the field.

Once an instrument has completed the certification process the breath analyst should assign the certification request in the LIMS. The certification paperwork should be scanned into the request and the request milestone rolled to draft complete. The instrument certification must be technically reviewed by another qualified analyst prior to the instrument being sent out for use. This technical review is documented in the LIMS. Once the certification is technically reviewed a certificate is generated stating the instrument is certified for use.

#### 3.4 INSTRUMENT REPAIR

Once an instrument is certified for use and placed in the field it is the responsibility of the breath test supervisors to keep the crime lab informed of operational problems with the instruments. Breath test operators are trained to contact their breath test supervisor with problems who in turn can contact the crime lab if they are unable to correct the problem themselves.

The crime laboratory has several options for troubleshooting an instrument and the steps used in instrument troubleshooting are generally left up to the individual breath analyst. Breath analysts can work with breath test supervisors and/or remotely access the DataMaster DMT using the DM Host software. If the instrument is deemed to need repair by the crime lab, the breath test supervisor will take the instrument out of service and return it to the crime laboratory for repair.

Instruments arriving at the crime laboratory for repair should follow the check-in procedure and then a qualified breath analyst should assess the instrument to determine what repairs are needed, if any. This troubleshooting is performed using training provided by the instrument manufacturer and often involves direct contact with the manufacturer.

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When the repair is completed, either by the factory or the crime lab, the instrument must undergo a certification prior to being placed in service at an agency. Exchanging the external accessories such as printers, keyboards and breath hoses do not require recertification because they do not alter the analytical components of the instrument. Software updates only require certification if they alter the analytical components of the instrument.

All repairs performed by the crime lab should be documented on the DataMaster Repair Form. Information about repairs completed by National Patent Analytical Systems, Inc. is scanned into the LIMS as part of the check-in paperwork.

#### 3.5 PREVENTATIVE MAINTENANCE

In order to ensure that instruments in the field remain in good working order the crime lab has instituted a preventative maintenance schedule. This ensures that every instrument is returned to the crime lab for a visual inspection and recertification at least every four years. If an instrument is returned to the laboratory for repair the preventative maintenance will be performed at that time and the four year period will be restarted. Preventative maintenance consists of a check-in procedure; visual inspection and repairs as needed; and certification.

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#### **SECTION 4**

#### **QUALITY ASSURANCE**

#### 4.1 EXTERNAL DRY GAS ETHANOL STANDARDS

Dry gas ethanol standards are used as external standards with instruments in the field and for linearity testing as part of the certification process performed at the crime lab. External dry gas ethanol standards are purchased from an ISO 17025 certified manufacturer, are NIST traceable, and come with a certificate of analysis. An accuracy check will be performed on each new external dry gas ethanol standard lot received by analyzing it five times on a certified DataMaster. The results of this accuracy check must fall within +/- 0.005 or 3% whichever is greater, of the target value adjusted for barometric pressure and the standard deviation must not be greater than 0.0030. The certificate of analysis and the results of the accuracy check are then scanned into the LIMS.

#### 4.2 WET BATH ETHANOL SIMULATOR SOLUTIONS

Commercially prepared wet bath ethanol simulator solutions are used for calibration of breath test instruments and for interference detected functional checks. Ethanol simulator solutions are purchased from a NIST traceable supplier and come with a certificate of analysis. When a new lot of simulator solution is received an accuracy check will be performed on one bottle from each lot. The accuracy check will consist of analyzing one bottle five times on a certified DataMaster. The results should read within +/- 0.005 or 3%, whichever is greater, of the expected value and the standard deviation must not be greater than 0.0030. The certificate of analysis and accuracy test will be scanned into the LIMS.

#### 4.3 SIMULATORS

The crime lab uses simulators manufactured by Guth Laboratories that are NIST traceable and come with a calibration certificate. Simulators are returned to Guth Laboratories annually for calibration and maintenance. Certificates of calibration for the simulators are scanned into the LIMS.

#### 4.4 BAROMETER

The barometer used for checking and adjusting the barometric pressure is purchased from an ISO 17025 certified manufacturer, NIST traceable and comes with a certificate of calibration. The barometer is sent out for calibration or replaced when the manufacturer calibration expires. Certificates of calibration are scanned into the LIMS.

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#### **SECTION 5**

#### TRAINING PROVIDED

#### 5.1 BREATH TEST SUPERVISOR TRAINING

One of the duties of the breath alcohol section is to train and certify breath test supervisors. Per 13 AAC 63.070 a breath test supervisor must complete a course approved by the scientific director. The course content is written and taught by the breath alcohol section and approved by the scientific director.

To be certified by the scientific director as a breath test supervisor the applicant must obtain a score of 75 percent or higher on a written examination covering the content of the course. The examination is written by the breath alcohol section and approved by the scientific director. Upon successful completion of the breath test supervisor course a list is provided to the Alaska Police Standard Council and a certificate is issued indicating the breath test supervisor is authorized to teach breath test operator courses.

The breath test supervisor certification expires at 11:59 p.m. on December 31 of the third year after issued. Per 13 AAC 63.080 to recertify as a breath test supervisor the applicant must complete a recertification course approved by the scientific director. This course is also taught by the breath alcohol section.

### 5.2 BREATH TEST OPERATOR TRAINING

Breath test operators are trained by breath test supervisors in accordance with 13 AAC 63.050 and 13 AAC 63.060. The breath alcohol section provides the approved training program and examination to breath test supervisors for this training.

To certify a breath test operator the breath test supervisor should complete a Request for Certification of Breath Test Operators on the DataMaster DMT form to the crime lab indicating that the applicant has successfully completed the certification or recertification course. The breath alcohol section will then issue or renew an operator certificate and operator number indicating that the applicant is certified by the scientific director as a breath test operator.

Per 13 AAC 63.050 a breath test operator certificate expires three years from the date issued.

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#### APPENDIX I

#### APPROVED ASSOCIATED EQUIPMENT

#### External Dry Gas Ethanol Standards

External dry gas ethanol standards are obtained from the breath alcohol section. External dry gas ethanol standards used by the breath alcohol section are purchased from an ISO/17025 certified manufacturer, are NIST traceable, and come accompanied by a certificate of analysis. Each lot received by the crime lab is approved for use by the breath alcohol section after an accuracy test is performed on the lot. For this reason only external dry gas ethanol standards provided by the breath alcohol section may be used with the evidential breath testing instruments.

#### **Mouthpieces**

Mouthpieces are obtained from the breath alcohol section or the Department of Public Safety Supply. The current mouthpieces used are part number GM-1000-100 purchased from Guth.

#### DataMaster Parts and External Accessories

All parts used for instrument repair are purchased from National Patent Analytical Systems, Inc. and are approved for use with the DataMaster DMT.

External accessories used with the DataMaster DMT include the breath hose and USB keyboard. Replacement parts are obtained from the breath alcohol section.

#### **External Printers**

The first external printer is provided by the breath alcohol section. It is an HP LaserJet Professional model number P1606dn. Replacement printers, paper and toner are the responsibility of the individual agency. Any compatible toner cartridges may be used with the printer. Replacement printers must be approved by the breath alcohol section prior to purchase or use to ensure they are compatible with the DataMaster DMT. Any compatible external printer can be used with the DataMaster DMT.

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#### **APPENDIX II**

#### BREATH ALCOHOL PROGRAM FORMS

#### **Internal Forms**

DataMaster Acceptance Form

DataMaster Check-In Form

DataMaster Repair Form

DataMaster Calibration Form

**DataMaster Certification Form** 

### **External Forms (posted on the crime lab website)**

DataMaster Change in Instrument Status Form

Request for Certification of Breath Test Operators on the DataMaster DMT Form

Request for Recertification of Breath Test Operators on the DataMaster DMT Form

Change in Operator Status Form



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#### **APPENDIX III**

### **REVISION HISTORY**

|                 | d Cover Sheet, updated page numbers and e of Contents, changed header, updated |
|-----------------|--|
|                 | formatting throughout document   |
|                 | d the sentence "Once the data is uploaded                                      |
| to the          | e crime lab it is no longer available in the DataMaster DMT memory."           |
| _               | d the location of working instructions from                                    |
|                 | ndix II to separate controlled document.                                       |
| 7 9 3.1 Added t | he statement "if coming from the field" to                                     |
| the sente       | ence ending"uploading the instrument to  |
| retri           | eve all information stored in memory".   |
|                 | e statements "The check-in documentation                                       |
|                 | e documented on the DataMaster Check-In  |
|                 | which is scanned into the LIMS and "or are                                     |
|                 | d to the laboratory from a factory repair"                                     |
|                 | he statement "This documentation is then                                       |
|                 | ically and administratively reviewed by a                                      |
| qua             | alified analyst." for the check-in form.                                       |
| 8 9 3.1 Chang   | ged statement about repair and check-in  |
| should          | l be documented on the check-in to "Any  |
|                 | performed in-house should be documented  |
|                 | ataMaster Repair Form." Changed check-in                                       |
|                 | cedure from initiating a verification of                                       |
| calibration     | on to "running a diagnostic and 5 tests of an 0.080 external standard"         |
| 8 9 3.1 Added t | he statement "This documentation is then                                       |
|                 | ically and administratively reviewed by a                                      |
|                 | ualified analyst." for the repair form.  |
| y.              | daimed analyst. For the repair form.   |
|                 | on the Calibration Form which is scanned                                       |
|                 | LIMS" in place of documented in the LIMS.                                      |
|                 | the statement "as measured at standard   |
|                 | re" to the sentence listing the external dry                                   |
|                 | standards utilized in linearity testing.                                       |
| 11 12 3.3       | Changed 0.999 to 0.9990.   |
|                 |  |

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| R1 Page | R0 page | location         | Revision made   |
|---------|---------|------------------|---|
| 11      | 12      | 3.3              | Changed operater to operator.   |
| 12      | 13      | 3.3              | Changed the minimum volume requirement low range from 1.0 L to 1.3 L.   |
| 12      | 14      | 3.3              | Amended the second sentence on that page as follows "The breath test analyst should ensure a 208 ppm ethanolcylinder is in place or follow the tank change procedure."  Removed the following sentence "This will initiate a  |
|         |         |                  | verification of calibration.  |
| 13      | 14      | 3.3              | Removed "The certification form filled out for the initial certification paperwork should be scanned into the calibration request image module if recalibration was required. If a repair is required the initial certification paperwork should be scanned into LIMS where appropriate." |
| 13      | 14      | 3.3              | Added "Any repair or recalibration should be documented on the appropriate forms and scanned into the LIMS. The instrument must complete a certification prior to being placed in service in the field."  |
| 14      | 15      | 3.4              | Replaced check-in sheet with DataMaster repair sheet.   |
| N/A     | 19      | Appendix II (R0) | Removed Appendix II from this manual. Working instructions are now a separate controlled document.  |
| 18      | 37      | Appendix II      | Changed Appendix III to Appendix II Breath Alcohol Program Forms.   |
| 18      | 37      | Appendix II      | Removed versions and effective dates for all forms.  All forms are tracked through a controlled documents list. Added DataMaster Repair Form and Operator recertification form.   |
| 19      | N/A     | Appendix III     | Added Revision History  |